

Remarks

The invention relates to devices for conducting assays, including qualitative, semi-quantitative and quantitative determinations of a plurality of analytes in a single test format. The instant method and apparatus claims refer to devices comprising one or more capillary channels, in which the relative hydrophobicity of regions within at least one capillary channel differs. In certain embodiments, this differing hydrophobicity is used to control the rate and/or direction of fluid flow through the devices.

The Examiner states that claims 74-93 as filed in the preliminary amendment were renumbered as 1-20 respectively. However, Applicant notes that although the claims were numbered from 74-93, there was a duplicate of claim 78. Thus 21 claims were actually filed. This is consistent with the Examiner's restriction which refers to claims 1-18 as group I and claims 19-21 as group II.

Claims 6 and 19-21 have been cancelled herein. Notwithstanding the foregoing, Applicant expressly reserves the right to pursue subject matter no longer claimed in the instant application in one or more applications that may claim priority hereto.

Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non Art-Based Remarks

Restriction

Applicant affirms the provisional election of Group I (claims 1-18) in response to the restriction requirement. Applicant has cancelled non-elected claims 19-21 herein.

35 U.S.C. § 112, second paragraph

The Examiner indicates that claim 6 should be deleted, as it is allegedly a duplicate of claim 5. Claim 6 has been cancelled.

Information Disclosure Statement

Applicant is filing herewith under separate cover the missing references mentioned by the Examiner and some additional references not previously submitted.

Art-Based Remarks

Obviousness-type double patenting

Applicant acknowledges the rejection of claims 1-18 as allegedly being unpatentable over U.S. Patents 6,156,270; 6,019,994; 5,885,527; and 5,458,852. Applicant believes that the listing of U.S. Patent No. 6,019,994 is a typographical error, and that the Examiner intends U.S. Patent No. 6,019,944. Should the Examiner agree with Applicant regarding the identity of the U.S. Patents at issue, and should the claims as presently submitted be otherwise allowable, Applicant will submit a terminal disclaimer. Applicant respectfully requests clarification of the rejection.

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 1-18 under 35 U.S.C. §102(b), as allegedly being anticipated by Kuhn *et al.*, U.S. Patent 5,202,268 (“the ‘268 patent”). For the sake of accuracy, Applicant notes that the ‘268 patent issued after the effective filing date of the present application (May 21, 1992) on an application filed before the filing date of the instant application, and so is presumably not prior art under 35 U.S.C. §102(b), but rather under 35 U.S.C. §102(e).

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also*,

MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of anticipation. Only once that *prima facie* case has been established does the burden shift to the applicant to rebut the *prima facie* case. *See, e.g., In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The Examiner points with particularity to the disclosure of a liquid flow path in the '268 patent through two porous layers, and to claim 4, which states that one of the layers may be hydrophilic and the other hydrophobic. Critical to the rejection is the Examiner's belief that the flow path through these porous layers is equivalent to flow through the "capillary channel" of the instant claims. Paper no. 9, page 4 ("[t]he taught flow path has been read on the claimed capillary channel."). Applicant respectfully disagrees with the view that a porous layer is equivalent to a capillary channel.

It is well established that terms in a claim must be interpreted in light of the specification, and the claims must be read as they would be interpreted by those of skill in the art. *See, MPEP §§ 2111 and 2111.01*. The Examiner's interpretation is contrary to the plain meaning of the term "channel" given to the term by those of skill in the art, and to the teachings of the instant specification.

As evidence of this fact, Applicants provide herewith a declaration of one of skill in the art, Dr. Kenneth F. Buechler, describing how the term "capillary channel" should be properly interpreted. In his declaration, Dr. Buechler begins with the common meaning of the term "channel," defined in Merriam Webster's Collegiate Dictionary as being "a usually tubular enclosed passage: CONDUIT." For the Examiner's convenience, a copy of this definition is provided herewith (APPENDIX 1). Dr. Buechler explains that the skilled artisan would understand that flow through a porous material as disclosed in the '268 patent is both tortuous and random, and that, therefore, a porous material is not equivalent to a "capillary channel." Dr. Buechler also notes that the instant specification clearly distinguishes between porous materials and capillary channels.

Thus, in view of the Buechler declaration, and the opinion that one of ordinary skill in the art would interpret the term “capillary channel” to be something different from a porous surface, it is concluded that the skilled artisan would readily acknowledge that the ‘268 patent does not anticipate the pending claims. In claim 1 of the present application, the capillary channel comprises a first capillary region comprising a hydrophilic surface, and a second capillary region comprising a hydrophobic surface adjacent to this first region. In contrast, the ‘268 patent discloses a first and second layer formed from “a composite structure of porous materials” through which fluid flows. ‘268 patent, column 1, lines 63-64. The “porous members” (column 2, line 57) making up this composite structure are entirely different from the “capillary channel” of the present claims. Indeed, the specification indicates that it is problems with devices containing porous materials that the present specification hopes to avoid. *See, e.g.*, specification, page 3. This same distinction exists for those claims dependent from claim 1, and claims 13-17.

Accordingly, the ‘268 patent does not anticipate the claims because it fails to teach each and every limitation. Thus, the Examiner is requested to reconsider and withdraw the rejection over Khun et al. (the ‘268 patent).

Applicant also notes that the Examiner has not indicated how the cited publication reads on claims 2 and 6 and their dependent claims. These claims describe the use of a hydrophobic surface to control the rate or direction of flow within a device. Likewise, the Examiner has not indicated how the cited publication reads on claims 3 and 12, which indicate that a hydrophobic region is used to delay fluid flow until rendered hydrophilic. As discussed by Dr. Buechler in paragraph 9 of his declaration, the ‘268 patent does not disclose these elements of the claims. Should the Examiner disagree, Applicant respectfully requests that the Examiner indicate where such elements may be found in the cited patent in a non-final office action, so that Applicant may have a reasonable opportunity to respond.

Because the cited ‘268 patent fails to teach each and every element of the present claims, Applicant respectfully submits that no *prima facie* case of anticipation has been established. Applicant therefore requests that the rejection under 35 U.S.C. §102 be reconsidered and

withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

By



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